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No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC AND PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTRODUCTION	1
ARGUMENT	6
THE MICHIGAN EXCEPTION IS PREEMPTED	6
A. There is no presumption against preemption here	6
B. The fraud-on-the-FDA Michigan exception is materially indistinguishable from the fraud-on-the-FDA claim in *Buckman*	8
C. The *Restatement* and cases addressing general tort law duties running from the company to the public are inapposite	9
D. The fraud-on-the-FDA exception presents the same intrusion on FDA's domain as did fraud-on-the-FDA claims in *Buckman*	17
E. The Second Circuit's decision should be reversed	22
CONCLUSION	24

TABLE OF AUTHORITIES

CASES Page

Bates v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005) 12
Buckman Co. v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ..... *passim*
Cook County, Ill. v. *United States ex rel. Chandler*, 538 U.S. 119 (2003) 15
Duronio v. *Merck & Co.*, No. 267003, 2006 WL 1628516 (Mich. Ct. App. June 13, 2006) 17, 22, 23
Frost v. *Railroad Comm'n*, 271 U.S. 583 (1926) 9
Garcia v. *Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) 17, 22, 23
Granfinanciera, S.A. v. *Nordberg*, 492 U.S. 33 (1989) 14
Medtronic v. *Lohr*, 518 U.S. 470 (1996) 12
Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 12
Sosa v. *Alvarez-Machain*, 542 U.S. 692 (2004) 15
Taylor v. *SmithKline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003) 14
Thigpen v. *Roberts*, 468 U.S. 27 (1984) 23
United States v. *Azeem*, 983 F.2d 1057 (4th Cir. 1993), *available at* 1993 WL 5902 21
United States v. *Chatterji*, 46 F.3d 1336 (4th Cir. 1995) 21
United States v. *Chicago, Milwaukee, St. Paul & Pac. R.R.*, 282 U.S. 311 (1931) 9
United States v. *Shah*, 68 F.3d 462 (4th Cir. 1995), *available at* 1995 WL 619955 .. 21
United States v. *Snyder*, 291 F.3d 1291 (11th Cir. 2002) 21

TABLE OF AUTHORITIES—continued

Page

Wyeth v. *Levine*, __ S. Ct. __, 2008 WL 161474 (Jan. 18, 2008) 5

STATUTES AND REGULATIONS

21 U.S.C. § 336 12
21 U.S.C. § 337 12
Mich. Comp. Laws § 600.2946(5) 3, 12, 14
21 C.F.R. § 10.85(k) 15
55 Fed. Reg. 4236 (Feb. 7, 1990) 21
8995 (Mar. 9, 1990) 21
24934 (June 19, 1990) 21
46245 (Nov. 2, 1990) 21
47542 (Nov. 14, 1990) 21
56 Fed. Reg. 2528 (Jan. 23, 1991) 21
19117 (Apr. 25, 1991) 21
20433 (May 3, 1991) 21
Fraud, Untrue Statements of Materials Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46191 (Sept. 10, 1991) 22
56 Fed. Reg. 58060 (Nov. 15, 1991) 21
61431 (Dec. 3, 1991) 21
63740 (Dec. 5 1991) 21
57 Fed. Reg. 3631 (Jan. 30, 1992) 21
3632 (Jan. 30, 1992) 21
6227 (Feb. 21, 1992) 21
11959 (Apr. 8, 1992) 21
14582 (Apr. 21, 1992) 21
19434 (May 6, 1992) 21
30741 (July 10, 1992) 21
32552 (July 22, 1992) 21
49485 (Nov. 2, 1992) 21
63 Fed. Reg. 30765 (June 5, 1998) 21

TABLE OF AUTHORITIES—continued

Page

Notice of Withdrawal of Approval of Two New Drug Applications, 66 Fed. Reg. 49030 (Sept. 25, 2001) 21

Notice of Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 1469 (Jan. 10, 2003) 3

RULE

Sup. Ct. R. 15.2 14

SCHOLARLY AUTHORITY

Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation & Tort Law*, 42 St. Louis U. L.J. 163 (1998) 16

OTHER AUTHORITIES

Restatement (Third) of Torts (1998) 5, 10, 11

Center for Drug Evaluation & Research, FDA, *Meeting Number 74 of: Endocrinologic & Metabolic Drugs Advisory Committee* ("EMDAC") (May 19, 2000), *available at* http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf 2

Center for Drug Evaluation & Research, FDA, *2005 Report to the Nation: Improving Public Health Through Human Drugs* (2005), *available at* http:www.fda.gov/cder/report/rtn/2005/rtn2005.pdf 19

FDA, *The Enforcement Story: Fiscal Year 2003* (2004), *available at* http://www.fda.gov/ora/about/enf_story/archive/ 21

TABLE OF AUTHORITIES—continued

Page

FDA, *The Enforcement Story: Fiscal Year 2005* (2006), *available at* http://www.fda.gov/ora/about/enf_story/archive/ 21

Office of Regulatory Affairs, FDA, *Application Integrity Policy* (1998), *available at* http://www.fda.gov/ora/compliance_ref/aip_procedures/AIPprocedures2004_0304.pdf 22

INTRODUCTION

Contrary to the suggestion of respondents and their *amici*, the preemption question presented here is quite narrow. Petitioners are not asking the Court to decide the relationship between FDA law generally and state-law tort liability. Those are issues the Court will confront elsewhere (see note 1, *infra*). Here the question is whether state courts have authority to adjudicate, as a predicate to assessing state tort liability against a manufacturer of a regulated pharmaceutical, claims that FDA was defrauded and would have ordered the drug withdrawn when, in fact, (i) FDA has found no such fraud, and (ii) the product was withdrawn for reasons independent of any purported fraud. This Court already has said that the answer to that question is: no. The Michigan exception requires the same state-law fraud-on-the-FDA determinations this Court held were preempted in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Respondents do not dispute that the Michigan exception requires a state-law determination of the same essential elements as in *Buckman*. See, *e.g.*, Resp. Br. 10, 14-15. Moreover, respondents acknowledge that "FDA never made a finding of fraud" in the Rezulin regulatory process, *id.* at 31, and "is not intending to do so," *id.* at 35. Indeed, the United States confirms that FDA has never found fraud relating to its regulation of Rezulin, U.S. Br. 5, 21, and "did not . . . rely on a finding of fraud" when it asked Warner-Lambert to withdraw the drug from the market, *id.* at 21. Nonetheless, respondents contend that state law is entitled to superintend this federal domain and allow a lay jury to speculate that the company actually committed fraud with respect

to its disclosure duties to FDA that caused FDA to withdraw Rezulin from the market. Respondents not only suggest that a jury *may* substitute its view for what FDA actually did; their theory of recovery in this case *demands* it.

Thus, although respondents paint their theories with a broad brush, the critical point here is that Rezulin was not withdrawn on account of fraud-on-the-FDA. See, *e.g.*, U.S. Br. 5, 21; Resp. Br. 31, 35 (acknowledging that FDA neither withdrew the drug due to fraud, nor made a finding that the agency was defrauded). Rather, Rezulin was withdrawn because it was a first-generation drug that later became "outmoded," by two newer diabetes medications. Ctr. for Drug Evaluation & Research ("CDER"), FDA, *Meeting No. 74 of Endocrinologic & Metabolic Drugs Advisory Committee* ("EMDAC Tr.") 82-83 (May 19, 2000), *available at* http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf.

Contrary to respondents' insinuation, the regulatory process worked with respect to Rezulin. When Rezulin was approved, it was the first in a new class of medications that targeted insulin resistance, an underlying cause of Type 2 diabetes—a life-threatening disease affecting 18 million Americans. Pet. Br. 13; U.S. Br. 4. FDA determined that the overall risk-benefit profile made Rezulin a worthwhile treatment option for many patients suffering from this serious condition. FDA also was acutely aware "since 1997" (when the drug was approved) of a potential risk of "[s]evere liver toxicity"—a fact FDA has explicitly acknowledged. See Pet. Br. 14 (alteration in original) (quoting HHS press release). Several years later, FDA approved two new second-generation drugs targeting insulin resistance. Because these newer drugs "offer[ed] a similar

benefit" as Rezulin with a decreased risk of liver toxicity, Warner-Lambert voluntarily discontinued marketing Rezulin and asked FDA to withdraw its approval of the drug. Notice of Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 1469, 1469 (Jan. 10, 2003). Thus, the record is clear that FDA did not withdraw its approval of Rezulin because of any finding of misconduct on the part of the manufacturer. See EMDAC Tr. 82-83; 68 Fed. Reg. at 1469; Pet. Br. 14-15; U.S. Br. 21 (FDA did not "rely on a finding of fraud" in withdrawing Rezulin).

Even though the agency has not found that petitioners materially breached any duty to it, respondents' claims would require a contrary state-law determination—*i.e.*, that petitioners defrauded FDA and that FDA withdrew Rezulin from the market on account of that purported fraud. Mich. Comp. Laws § 600.2946(5)(a) (requiring proof that the manufacturer "intentionally withh[eld] from or misrepresent[ed] to [FDA] information concerning the drug that is required to be submitted under the federal food, drug and cosmetic act [citing FDCA provisions], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted"). This attempt to inject state law into the limited, but exclusively, federal domain concerning the enforcement of duties owed to FDA by regulated entities is preempted. As *Buckman* teaches, because of the exquisitely complex scientific and public health issues FDA must balance, juries applying state law are not free to second-guess this federal process and substitute their view of what FDA might have done for what the agency *actually* did. See *Buckman*, 531 U.S. at 347-48; *id.* at 354 (Stevens, J., concurring in judgment) (preemption applies where jury is

required, as here, to "speculat[e] as to the FDA's behavior" and thus "second-guess[es] the FDA's decisionmaking").

In the absence of any official agency action finding fraud in the regulatory process and withdrawing Rezulin from the market on account of such fraud, there is no way that respondents can satisfy the Michigan exception without intruding into federal issues of regulatory compliance committed exclusively to FDA. See *id.* at 354 (Stevens, J., concurring in judgment). In other words, because respondents' ability to satisfy Michigan's "fraud-on-the-FDA" turns not on FDA's actual findings, but on a "counterfactual situation" antithetical to the "agency's explicit actions," there is no question that the exception is preempted as applied here. *Id.*; accord U.S. Br. 20.

In arguing otherwise, respondents urge this Court to adopt the Second Circuit's approach. First, respondents (and their *amici*) treat the "presumption against preemption" as somehow protecting these intrusions into FDA's exclusive domain from challenge. As *Buckman* made clear, however, state-law efforts to police the "inherently federal" disclosure duties owed exclusively to the agency deserve no presumption against preemption. 531 U.S. at 347. Moreover, any such presumption would be overcome here, given the depth of interference with FDA functions and the inevitable risk of conflicting findings between FDA and juries.

Next, respondents, as did the court below, imagine "distinctions" between the stand-alone fraud-on-the-FDA claim at issue in *Buckman* and the fraud-on-the-FDA exception to Michigan's product liability defense. But, as exhaustively detailed in our opening brief and the briefs of our *amici*, these distinctions

make no material difference to the preemption analysis. None alters the fundamental point that the proof ultimately required for respondents to establish liability under Michigan law is the same as was found to be impermissible in *Buckman*.

Finally, respondents and their *amici* urge that applying *Buckman* here would undo state-law regulatory compliance defenses generally, negligence *per se* doctrines, and the *Restatement (Third) of Torts*. These claims are wrong. First, the *Restatement* provision on which they rely states plainly that "the matter of federal preemption of state products liability law" is "beyond the scope of this Restatement." *Restatement* § 4, cmt. *e* (1998). In any event, the key distinction between this case and the state-law issues respondents invoke is that the duty that respondents claim was breached is owed exclusively to FDA, not to the public. Whatever rule might apply to state-law efforts to enforce federally created duties owed to the public in other settings, they cannot justify a state law that authorizes juries to inquire into enforcement issues delegated exclusively to FDA when the agency has not itself found that a violation occurred or enforcement is warranted.[1]

In actuality, respondents simply want to relitigate *Buckman*. They argue that the same proof of fraud-on-the-FDA that gave rise to preemption in *Buckman*

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[1] Resolving the constitutionality of Michigan's exception in this case does not implicate whether a preempted conflict may arise between state law and other FDCA-imposed duties such as those involving the adequacy of labeling under federal law. *Compare, e.g.*, Br. Am. Ass'n for Justice 20-34 (wrongly implying that petitioners seek to preempt state tort law). Those issues, however, are raised in *Wyeth* v. *Levine*, __ S. Ct. __, 2008 WL 161474 (Jan. 18, 2008).

should not give rise to preemption in this case, even though it presents the same intrusion into areas of exclusively federal concern and poses the same risks of overburdening the agency. Indeed, respondents' *amici* explicitly argue, in direct contravention of *Buckman*, that fraud-on-the-FDA "is neither inherently nor uniquely a matter of federal concern" and that "the facts that establish state tort liability may also be characterized as 'fraud on the FDA.'" Nat'l Conf. State Leg. Br. 17. This Court should reject this challenge to *Buckman* and reverse the decision of the Second Circuit.

ARGUMENT

THE MICHIGAN EXCEPTION IS PREEMPTED

Nothing in respondents' brief undermines our showing that this case presents a straightforward application of the preemption principles of *Buckman*. Preemption "inevitably" occurs here, as it did in *Buckman*, because the Michigan exception as applied in this case intrudes on an exclusively federal realm involving duties "originat[ing] from, . . . governed by, and terminat[ing] according to federal law." 531 U.S. at 347, 350-51. A fundamental flaw in the analysis of respondents (and their *amici*), like that of the court of appeals below, is to treat this case as a garden-variety state tort action involving duties as between private parties. We address respondents' specific points in turn.

A. There is no presumption against preemption here. In *Buckman*, this Court held that there is no presumption against preemption where a jury is asked to decide whether there has been a material fraud on FDA during the regulatory process. To the contrary, the relationship between a regulated

entity and FDA is "inherently federal in character" and "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Because the Michigan exception turns on this self-same impermissible inquiry, *Buckman* plainly controls here and there is no presumption against preemption.[2]

In an effort to avoid this analysis, respondents and their *amici* urge that this case be viewed not from the perspective of duties owed to FDA, but as "part of a traditional state tort system aimed at redressing violations of duties of care owed by drug manufacturers to the individuals who use their products." Resp. Br. 17-18; *e.g.*, Nat'l Conf. State Leg. Br. 6 ("Michigan's statute is a classic exercise of state police power"); Kan. Br. 13 (asserting that "this case involves one of the States' most traditional police powers—tort law"). This is wrong, and this fundamental error permeates their arguments. See *infra*. As the United States aptly puts it, "the question here is not whether traditional tort claims are preempted; it is whether the portion of the Michigan statute that requires a finding of fraud on FDA is preempted." U.S. Br. 14. Accordingly, this is not an area of traditional state authority and is not presumptively permissible.

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[2] Respondents' *amici* mistakenly read *Buckman* as applying a presumption that then was "overcome" because "state law inevitably and necessarily conflicts with federal law." Kan. Br. 6. Although we also would meet that standard, *see* Pet. Br. 38 n.14, *Buckman* plainly holds that "no presumption against preemption obtains in this case." 531 U.S. at 348.

B. The fraud-on-the-FDA Michigan exception is materially indistinguishable from the fraud-on-the-FDA claim in *Buckman*. We previously demonstrated why none of the distinctions drawn by the court of appeals between this case and *Buckman* affects the proper preemption analysis. Pet. Br. 41-50. In both cases, the Michigan exception requires the fact-finder to make exactly the same impermissible fraud-on-the-FDA determination.

Echoing the court of appeals, respondents contend that the Michigan exception is not preempted because the complaints here depend on underlying "traditional" common-law tort claims as the ultimate basis for recovery, whereas the claim at issue in *Buckman* was (they assert) limited to allegations that FDA was defrauded. Resp. Br. 21-23; *id.* at 32-33; see Pet. Br. 41-44 (addressing this point). Respondents simply elevate form over substance. *Buckman* hinged on the unavoidable interference that state-law adjudication of questions of fraud-on-the-FDA would pose to the federal scheme. See Resp. Br. 17-18, 21-22. Proof that federal duties to FDA were violated will require as much second-guessing by lay jurors, and be equally harmful to the agency's balance of statutory objectives, whether litigated as a part of the defense or the cause of action. See, *e.g.*, *id.* at 11, 13, 16-17. Federal disclosure requirements were "critical element[s]" of plaintiffs' underlying claim in *Buckman*, 531 U.S. at 353, and are equally "critical" aspects of respondents' case. See Resp. Br. 22; U.S. Br. 11.

Respondents also contend that it matters that the fraud-on-the-FDA inquiry comes into play under Michigan law only if the pharmaceutical defendant first invokes the statutory defense against product liability. See *id.* at 12-13, 22. As put by their *amici*,

federalism principles therefore dictate that "[t]he greater power," which Michigan exercised by providing the statutory defense, "necessarily encompasses the lesser power to impose conditions on the defense"—*i.e.*, to allow a showing of fraud-on-the-FDA. Kan. Br. 7. This is wrong. See Pet. Br. 47-50.

> It long has been settled in this court that the rejection of an unconstitutional condition imposed by a state upon the grant of a privilege, even though the state possess[es] the unqualified power to withhold the grant altogether, does not annul the grant. . . . Broadly stated, the rule is that the right to continue the exercise of a privilege granted by the state cannot be made to depend upon the grantee's submission to a condition prescribed by the state which is hostile to the provisions of the federal Constitution.

United States v. *Chicago, Milwaukee, St. Paul & Pac. R.R.*, 282 U.S. 311, 328-29 (1931) (citations omitted); accord *Frost* v. *Railroad Comm'n*, 271 U.S. 583, 595-99 (1926).

Put another way, the fraud-on-the-FDA exception to the Michigan statute is not a lesser power over which Michigan has exclusive control. Rather, it is a condition that, as applied in this case, requires the jury to make an unconstitutional incursion into a matter of exclusively federal concern. Therefore, it is preempted.

C. The *Restatement* and cases addressing general tort law duties running from the company to the public are inapposite. This case concerns a narrow aspect of a single federal scheme: the disclosure duties regulated entities owe to FDA and the agency's enforcement of those requirements under FDCA. Nonetheless, respondents draw upon

broader and more general state-law tort principles that have no bearing on the preemption inquiry at issue here. Resp. Br. 24-29, 39-40.

1. Contrary to respondents' claims, applying preemption in this case would not interfere with "traditional" state tort law as reflected in the *Restatement* § 4. See Resp. Br. 10, 28-31. That provision is simply a generic statement of state tort law and, by its own terms, does not speak at all to the question of federal preemption, much less preemption under FDA's regulation of federal disclosure requirements. Section 4 of the *Restatement* provides that evidence of a manufacturer's compliance or non-compliance with an applicable "product safety statute or administrative regulation" is relevant in gauging whether a product is defective or not under state law. *Restatement* § 4. Comment *e* to that section further states that, "when the deliberative process that led to the safety standard . . . was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard[,] . . . compliance with regulation is entitled to little or no weight." *Id.* § 4, cmt. *e*. Respondents and their *amici* seize on this language to suggest that applying preemption in our context would radically undermine traditional tort principles permitting compliance inquiries, and not applying preemption would impose no additional burdens or obstacles on FDA. Resp. Br. 15, 18, 30-31.

In truth, this line of argument is simply a *non sequitur* in the context of this case. The first sentence of comment *e*—in language notably omitted from the briefs of respondents and their *amici*—states that "[a]n important distinction must be drawn between the subject addressed in [this section] and the matter of federal preemption of state products

liability law." *Restatement* § 4, cmt. *e*. Section 4 addresses whether and when state tort claims should incorporate product safety standards "*as a matter of state tort law*." *Id.* (emphasis added). It does not address whether and when a state tort claim that incorporates such standards is preempted *as a matter of federal law*. *Id.*[3] As comment *e* points out, preemption must be decided by reference to the "complex set of rules and standards" of federal law, a topic simply "beyond the scope of this Restatement." *Id.* It can hardly be said that a finding of preemption in this case would disturb traditional tort law—when the very provision on which respondents rely recognizes this result. Indeed, none of the cases collected in the *Restatement* annotations remotely involves the issue of fraud on a federal agency.

Put another way, the fraud-on-the-FDA exception at issue here relates not to the duty owed from the manufacturer to the public—the traditional concern of tort law—but instead relates exclusively to the duty owed from the manufacturer to the agency, an area of purely federal concern in the FDCA context presented here. The *Restatement* therefore has no application in this case and lends no support to the validity of the Michigan fraud-on-the-FDA exception. See U.S. Br. 30.

2. Ignoring *Buckman*, respondents also contend that "this Court has long recognized the viability of state-law claims premised on the failure to comply

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[3] Moreover, obviously nothing in the preemption rule we propose or that this Court embraced in *Buckman* remotely interferes with how a state court treats products regulated by *state* agencies. Claims involving fraud on a state agency are not the concern of FDA or federal law. Thus, the *Restatement*'s general rule may apply to many situations where there is no basis for a claim of federal preemption.

with federal regulations" and this precludes preemption here. Resp. Br. 24. None of the cases to which respondents point involves the question of whether the regulated entity committed fraud with respect to FDA (or any other agency) in breach of federal duties created by federal law and owed to the agency alone. See *Buckman*, 531 U.S. at 347-48. For instance, in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), the Court permitted plaintiffs to pursue injury claims based on the alleged simultaneous violation of federal and state duties governing labeling outside the pharmaceutical context—*i.e.*, warnings which the regulated entity is compelled to provide the public. *Id.* at 442. Breach of duties owed to the public also was the basis for the claims in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996), as well as in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984).

Here, by contrast, the Michigan statutory exception is not regulating disclosures owed to the *public*. It instead seeks to enforce matters entirely reserved to the agency. See Mich. Comp. Laws § 600.2946(5)(a) (requiring proof that the manufacturer "intentionally withh[eld] from or misrepresent[ed] to [FDA] information concerning the drug that is required to be submitted under the [FDCA] [citing FDCA provisions], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted"). Of note, respondents ignore the pertinent federal statutes, under which "all ... proceedings for the enforcement, or to restrain violations, of [FDCA]" lie with FDA alone, 21 U.S.C. § 337, and the agency has complete discretion to commence or forgo formal enforcement in the face of a violation as it determines appropriate, *id.* § 336. See, *e.g.*, Pet. Br. 10-11, 24-26, 28-29. The cases upon

which respondents rely do not involve such duties, and thus none features the intrusions into the federal scheme at issue here.

Given the comprehensive and exclusive oversight FDA exercises over every aspect of the New Drug Application ("NDA") review process and post-marketing disclosures to the agency, see, *e.g.*, U.S. Br. 1-4, 15-17; Pet. Br. 3-11, injecting state-law into these core FDA functions—and allowing lay juries to second-guess the delicate balances reached by the agency about alleged misrepresentations to the agency and the proper means of enforcement—would "inevitably conflict" with the federal scheme. U.S. Br. 10, 18-22.

3. It is no answer to posit that, because courts have sometimes admitted evidence of compliance with federal safety standards on the issue of product defect, there is no risk of burdening the agency by seeking to litigate the issue of fraud-on-the-agency. Resp. Br. 27, 39-40. There is a significant difference between showing compliance or non-compliance with the terms of an FDA approval, as evidence of product defect under state law, and showing compliance or non-compliance with regulatory requirements governing FDA approval process, and that approval should never have been granted *ab initio*. See U.S. Br. 13 n.2, 18.

Compliance with the terms of an FDA approval may be established through objective evidence. The labeling of an FDA-approved medication either conforms to the FDA-approved language or it does not, and the chemical formulation of the medication is either the same as that approved by FDA or not. These assessments ordinarily do not affect the relationship between the manufacturer and the agency, implicate the testimony of agency officials, or

require speculation by the fact-finder as to how the agency will enforce its statute and regulations. Indeed, here, respondents never questioned the threshold determination that, under the Michigan statute, Rezulin was in compliance with the terms of FDA approval.[4] If a medication is in fact non-compliant with the terms of FDA approval, depending on the circumstances, there may not be a federal law prohibition on a state imposing remedies. See Resp. Br. 24-25 (citing *Lohr*, 518 U.S. at 495). For example, outside the context of this case, a manufacturing flaw claim—*i.e.*, that the drug or device plaintiff used did not conform to the FDA-approved parameters—may survive the pertinent express or implied preemption analysis.

In contrast, the point at issue here—the adequacy of compliance with regulatory requirements governing the FDA approval process, and FDA's

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[4] Though respondents do not dispute the point, one *amicus* argues that to qualify for Michigan's defense against product liability the pharmaceutical company first must establish that it did *not* defraud FDA. *See* AARP Br. 7, 10, 14-15; *contra Taylor* v. *SmithKline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003) (unless an exception "applies[,] . . . a manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller"). Respondents never pressed this point below, nor have they ever suggested that petitioners did not qualify for protection under Mich. Comp. Laws § 600.2946(5). Rather, respondents always have argued that the fraud exception *overcomes* the otherwise applicable statutory defense. *See* Pet. App. 23a-24a; *see also Amicus* Br. of Am. Ass'n Justice 2 ("When a plaintiff does not proffer evidence of misconduct, a court will dismiss a plaintiff's products liability action."). Accordingly, this point has been waived. *See Granfinanciera, S.A.* v. *Nordberg*, 492 U.S. 33, 38-39 (1989); Sup. Ct. R. 15.2.

possible response to a conjectural finding of non-compliance—simply cannot be proved by objective evidence in the absence of official agency action. Any such inquiry would require the jury to make numerous invasive, subjective, expert determinations for which it is institutionally ill-equipped, raising a substantial risk of a state-law finding that FDA was defrauded when the federal government has determined there was no fraud. See U.S. Br. 21-23.[5]

Respondents and their *amici* erroneously suggest that, even without FDA's involvement in litigation, these inquiries are "objective ones" that can be proved through "expert evaluation." AARP Br. 17; see Resp. Br. 40 (arguing that the exception could be satisfied without burdening the agency because there "are so many former FDA medical officers" available to testify). Such proofs are by no means objective. Even most *current* FDA employees are institutionally incapable of answering what the *agency*, as such, would have done; it is fanciful to imagine that *former* employees could properly do so.[6] And, even though

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[5] That federal juries may be called upon to adjudicate criminal guilt *after* the federal government concludes that it has been defrauded and elects to pursue an enforcement action does not, as respondents suggest, cut against preemption. *See* Resp. Br. 26, 39. In that circumstance there is no risk the jury will find fraud-on-the-FDA which the agency itself has not concluded exists. *See generally Buckman*, 531 U.S. at 354 (Stevens, J., concurring in judgment); *accord* U.S. Br. 20. In contrast, absent preemption, private parties would be free to proceed even when the agency itself has not concluded it has been defrauded and would not pursue enforcement. *Cf. Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 727 (2004); *Cook County, Ill.* v. *United States ex rel. Chandler*, 538 U.S. 119, 131 (2003) (recognizing "self-interest" inherent in suits brought by private parties).

[6] *See generally* 21 C.F.R. § 10.85(k) ("A statement or advice given by an FDA employee orally, or given in writing but not

such witnesses could not definitively speak for the agency—and therefore would trespass into FDA's exclusive domain—to the extent such speculation was not properly barred under a *Daubert* challenge, this testimony could be unreliably credited by a lay jury. Indeed, "we may be confronted with the spectacle of one former FDA official testifying what action she would have taken, while another retired FDA official explains that he would have done something quite different." Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation & Tort Law*, 42 St. Louis U. L.J. 163, 177 (1998) ("These counterfactual inquiries are not the stuff of which confidently accurate outcomes are reached in litigation."). All the while, FDA officials who actually make the decisions are fighting to stay out of court so that they may focus their time and attention on serving the public interest by enforcing the FDCA. U.S. Br. 21-22; Pet. Br. 17, 35 & n.13. In the end, there is no appropriate method by which a lay jury could determine whether fraud-on-the-FDA occurred, and how the agency would have remedied such fraud, without answers from the agency itself.

As such, state-law determinations that a manufacturer committed fraud-on-the-FDA, and that a medication would not have been approved absent such fraud, necessarily intrude on FDA's ability to police misconduct consistently with its statutory objectives. See *Buckman*, 531 U.S. at 349; *id.* at 353-54 (Stevens, J., concurring in judgment); see also U.S.

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under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.").

Br. 18 ("Notwithstanding fraud, FDA may decide that a drug's health benefits counsel against removing it from the market . . . ."). On the other hand, "[i]f the FDA determines both that fraud has occurred and that such fraud requires removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." *Buckman*, 531 U.S. at 354 (Stevens, J., concurring in judgment). In that circumstance, which is not present here, preemption may not be warranted. Indeed, this is the precise position taken by the Sixth Circuit in *Garcia* v. *Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), and the Michigan Court of Appeals in *Duronio* v. *Merck & Co.*, No. 267003, 2006 WL 1628516 (Mich. Ct. App. June 13, 2006) (per curiam), both of which concluded that the Michigan fraud-on-the-FDA exception (i) is preempted when, as here, the agency has not made a finding of fraud but (ii) is not preempted when the agency has found that a manufacturer committed fraud that would have resulted in withdrawal of approval. See *Garcia*, 385 F.3d at 966-67; *Duronio*, 2006 WL 1628516, at *5.

As respondents' acknowledge, Rezulin was not withdrawn on account of fraud-on-the-FDA, nor did FDA find any such fraud. U.S. Br. 5, 21; Resp. Br. 31, 35. Respondents' attempt to invoke the Michigan exception, accordingly, is preempted.

D. The fraud-on-the-FDA exception presents the same intrusion on FDA's domain as did fraud-on-the-FDA claims in *Buckman*. As the United States has made clear, "the conflict is the same as with the stand-alone fraud-on-the-FDA

claims in *Buckman*." U.S. Br. 16-17.[7] Despite respondents' arguments to the contrary, Resp. Br 37-40, permitting state-law proof of fraud-on-the-FDA poses a serious risk of overburdening the agency. As this Court recognized in *Buckman*, if plaintiffs were allowed to bring a claim against manufacturers for failing to disclose information to FDA, manufacturers would have an incentive during the approval process to dump on the agency all possibly relevant information, regardless of whether that information is viewed by the agency as required or material to its deliberations. 531 U.S. at 350-51. This "deluge of information," which the agency "neither wants nor needs," would result in "additional burdens on the FDA[]" and could delay the approval process. *Id.*; PhRMA Br. 30 ("Under the FDCA, responsibility rests with FDA—not the States—to balance the need for material information against the burden of excessive disclosure in the drug approval process."). Identical concerns apply here: if a manufacturer could lose its statutory defense if a jury were to conclude that it failed to disclose some piece of information to the agency, the manufacturer will

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[7] Wrenching a few snippets out of context, respondents urge that any deference to the brief of the United States "is unwarranted because, just last year, the United States advocated a contrary position" in a district court *amicus* brief. Resp. Br. 36 (citing U.S. Br., *Perry* v. *Novartis Pharms.*, No. 05-5350 (E.D. Pa. filed Sept. 21, 2006)). First, the government's position here is entirely consistent with that which it took in *Buckman*. *See* U.S. Br. 16-30, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, No. 98-1768 (U.S. filed Sept. 13, 2000). Second, *Perry* did not touch upon fraud-on-the-FDA, but hinged upon the asserted preemption of failure to warn claims, a subject not implicated here. Finally, read in context, it is plain that the government's point in the *Perry* brief was simply that courts must look to FDA's actions and not speculate about what it might have done divorced from what it actually did do.

have a significant incentive to provide the agency with any and all available information—whether or not that information is required or material in the agency's view.

Respondents contend that the case for interference is somehow less here than in *Buckman* because this case involves the rigorous NDA process, which is not as "speedy" as the abbreviated procedure applicable to the devices at issue in *Buckman*. See Resp. Br. 38-39. Even if true, this does nothing to undo the point. First, a primary mission of FDA is to review NDAs "promptly" and to act on them "in a timely manner," expediting the approval process without sacrificing the quality or rigor of the agency's review. See, *e.g.*, CDER, FDA, *2005 Report to the Nation: Improving Public Health Through Human Drugs* (2005) (mission statement), *available at* http://www.fda.gov/cder/reports/rtn/2005/rtn2005.pdf. Second, the dangers of impeding FDA in the NDA setting may be more acute than they were in the context at issue in *Buckman*, which involved only devices that were "substantially equivalent" to those already on the market. 531 U.S. at 344-47. Here, by contrast, delays in the NDA process would deny patients access to new, life-saving medications. Indeed, first-generation drugs such as Rezulin may be given "priority review" in light of the significant public health interest in promptly bringing such treatments to market. Pet. Br. 13. Given the bulk of a typical NDA, see *id.* at 5 n.1, these federal regulatory goals would be, if anything, more seriously undermined in the NDA context if manufacturers were encouraged to submit yet more reams of information to FDA for only defensive, and not legitimate regulatory, reasons. *Buckman*, 351 U.S. at 350-51.

Thus, the fraud-on-the-agency exception of the Michigan statute, as applied here, poses the same risks of agency interference as the fraud-on-the-FDA claim in *Buckman*. As in *Buckman*, the issue is not whether the agency is already being deluged by unnecessary materials or overwhelmed by subpoenas for staff testimony, but whether state law poses a serious risk that such burdens will arise. 531 U.S. at 350-51; see also U.S. Br. 21-22. If application of the Michigan exception is upheld in this case, in the absence of an official agency finding of non-compliance with regulatory disclosure requirements, any potential defendant that can be sued under that statute will have a strong incentive to create a record of over-disclosure to FDA. That is a burden the federal scheme preempts.

Respondents and their *amici* further contend that competing state-law determinations would not impinge the agency's mission because FDA "rarely if ever" finds itself defrauded. Resp. Br. 31-32. This statement, even if true, does nothing to advance respondents' argument. In the first place, the proper inference is that most pharmaceutical companies do not attempt to defraud FDA, not that the agency is failing to police the FDCA's disclosure requirements. See, *e.g.*, Pet. Br. 4-11, 23-27; U.S. Br. 3-4, 24.

If the implication is that FDA is turning a blind eye to efforts to deceive it, that is demonstrably false and insulting. U.S. Br. 24 n.7. FDA has instituted a number of measures designed to assure data integrity and detect misconduct with respect to the entities it regulates. Where it deems appropriate, the agency has exercised this authority in a number of ways, ranging from issuing warning letters to barring certain investigators from conducting clinical trials to removing products from the market and imposing

fines and other sanctions. See Pet. Br. 9-11. For example, according to the Federal Register, on at least 22 occasions since 1990, FDA has issued formal findings that a sponsor misrepresented information to FDA and the agency withdrew approval of the application on that basis, and FDA's annual "Enforcement Story" lists a number of prosecutions it undertook where it believed the regulated entity had made misrepresentations to the agency.[8] Apart from criminal prosecutions, FDA has implemented an

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[8] *E.g.*, FDA, *The Enforcement Story: Fiscal Year 2005*, at 6-32 (2006) ("Pharmaceutical Firm Found . . . Falsifying Records"), *available at* http://www.fda.gov/ora/about/enf_story/archive/; FDA, *The Enforcement Story: Fiscal Year 2003*, at 6-32 (2004); *United States* v. *Snyder*, 291 F.3d 1291 (11th Cir. 2002) (addressing sentencing issues with respect to company officials found to have made false statements to FDA); *United States* v. *Shah*, 68 F.3d 462 (4th Cir. 1995) (unpublished table decision) (per curiam) (same), *available at* 1995 WL 619955; *United States* v. *Chatterji*, 46 F.3d 1336 (4th Cir. 1995) (same); *United States* v. *Azeem*, 983 F.2d 1057 (4th Cir. 1993) (unpublished table decision) (per curiam) (same), *available at* 1993 WL 5902; *see also* Notice of Withdrawal of Approval of Two New Drug Applications, 66 Fed. Reg. 49030, 49030 (Sept. 25, 2001) (FDA stating withdrawal occurred after it determined the company "submitted untrue statements of material fact in several applications filed with the agency" which "provided sufficient justification to question the reliability" of all application data); 63 Fed. Reg. 30765 (June 5, 1998); 57 Fed. Reg. 49485 (Nov. 2, 1992); 57 Fed. Reg. 32552 (July 22, 1992); 57 Fed. Reg. 30741 (July 10, 1992); 57 Fed. Reg. 19434 (May 6, 1992); 57 Fed. Reg. 14582 (Apr. 21, 1992); 57 Fed. Reg. 11959 (Apr. 8, 1992); 57 Fed. Reg. 6227 (Feb. 21, 1992); 57 Fed. Reg. 3632 (Jan. 30, 1992); 57 Fed. Reg. 3631 (Jan. 30, 1992); 56 Fed. Reg. 63740 (Dec. 5 1991); 56 Fed. Reg. 61431 (Dec. 3, 1991); 56 Fed. Reg. 58060 (Nov. 15, 1991); 56 Fed. Reg. 20433 (May 3, 1991); 56 Fed. Reg. 19117 (Apr. 25, 1991); 56 Fed. Reg. 2528 (Jan. 23, 1991); 55 Fed. Reg. 47542 (Nov. 14, 1990); 55 Fed. Reg. 46245 (Nov. 2, 1990); 55 Fed. Reg. 24934 (June 19, 1990); 55 Fed. Reg. 8995 (Mar. 9, 1990); 55 Fed. Reg. 4236 (Feb. 7, 1990).

"Application Integrity Policy" designed to uncover and address instances of fraud on the agency and untrue statements of material fact in applications submitted for agency review and approval. See Office of Regulatory Affairs, FDA, *Application Integrity Policy* (1998), *available at* http://www.fda.gov/ora/compliance_ref/aip_procedures/AIPprocedures2004_0304.pdf; see also Fraud, Untrue Statements of Materials Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46191 (Sept. 10, 1991).

E. The Second Circuit's decision should be reversed. If the Court determines that the Michigan fraud-on-the-FDA exception is preempted as applied in this case, there is no need to remand for consideration of the severability of the exception or the validity of the remainder of the statute. Remand would be unnecessary with respect to this as-applied challenge because it is already settled that the preempted applications of the fraud-on-the-FDA exception are severable from the remainder of the statute. As the district court below recognized, see Pet. App. 36a, the Sixth Circuit has already held that the fact that the exception is preempted when FDA has not itself found fraud does not require invalidation of other applications or provisions of the statute. *Garcia*, 385 F.3d at 966-67. The Michigan Court of Appeals has concurred in that judgment. *Duronio*, 2006 WL 1628516, at *5.

The Second Circuit acknowledged that its own precedent "mandated deference" and "instructed [it] to defer conclusively to another circuit's judgment . . . when that court of appeals' decision addressed questions of state law from a state within that circuit." Pet. App. 11a (emphasis omitted). This Court has similarly deferred to the judgment of a circuit court concerning the interpretation of state

law within that court's jurisdiction. See Pet. Br. 50 n.18 (collecting cases). There is thus no doubt that, if the Court finds that the exception is preempted as applied in this case (but not when FDA has found through official agency action that fraud has been committed and has withdrawn the drug on that basis, see *Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring in judgment)), the remainder of the statute would remain valid under the Sixth Circuit's interpretation of Michigan law. *Garcia*, 385 F.3d at 966-67; see also *Duronio*, 2006 WL 1628516, at *5.[9] Remand is therefore unnecessary, as the final result—restoration of the district court's judgment—is inexorably ordained. See generally *Thigpen* v. *Roberts*, 468 U.S. 27, 32-33 (1984) (remand unnecessary where issue was argued before the lower courts and could be "decided by a straightforward application of controlling precedent").

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[9] Respondents' argument that petitioners have somehow waived this issue, by failing to include it in the question presented, Resp. Br. 43, is specious. The issue was briefed and argued in the lower courts, *id.* at 42; it was identified again in the petition to this Court, Pet. 18-19; and respondents themselves raised it in their question presented, Resp. Br. i ("Whether federal regulation of drugs impliedly preempts application of the exception to the defense provided under the Michigan statute, *while leaving the defense itself intact.*") (emphasis added).

CONCLUSION

For the foregoing reasons and those presented in petitioners' opening brief, the Second Circuit's decision should be reversed.

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February 8, 2008